

December 8, 2014

**BY E-MAIL (sullivanvysdchambers@nysd.uscourts.gov)**

Honorable Richard J. Sullivan, U.S.D.J.  
United States District Court  
Southern District of New York  
40 Foley Square  
New York, NY 10007

Re: *Roche Diagnostics GmbH v. Enzo Biochem, Inc., et al.*, 04 Civ 4046 (RJS) (S.D.N.Y.)

Dear Judge Sullivan:

Pursuant to Sections 2.D and G of the Court's Individual Practices, the parties jointly submit this letter concerning Roche's request for leave to supplement its invalidity contentions in light of the Supreme Court's decision in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014). Enzo's counsel Michael J. Dell, Jonathan S. Caplan and Christine Willgoos and Roche's counsel Robert J. Gunther, Jr., Christopher R. Noyes and Omar A. Khan met and conferred regarding this issue on November 24, 2014, but were unable to resolve it.

**A. Roche's Position**

Roche respectfully requests leave to supplement its invalidity contentions in light of the Supreme Court's decision in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014), which was decided after the parties had fully briefed their claim construction disputes and long after Roche served its initial invalidity contentions in May 2013. In *Nautilus*, the Court held that a patent is invalid for indefiniteness when it "fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id.* at 2124. In doing so, the Court changed the prevailing standard for indefiniteness, *i.e.* that a patent claim is indefinite "**only** when it is 'not amenable to construction' or 'insolubly ambiguous.'" *Id.* at 2127. In explaining its more rigorous standard that would allow for more indefiniteness challenges, the Court noted, "[t]o tolerate imprecision just short of that rendering a claim 'insolubly ambiguous' would diminish the definiteness requirement's public-notice function." *Id.* at 2130. Under the new standard, Roche has additional indefiniteness defenses with respect to Enzo's '523 patent. *See* Ex. 1.

The Court should grant Roche leave to serve its supplemental invalidity contentions because: (1) an intervening change in the law provides good cause to supplement invalidity contentions, *see O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006) ("refusing to allow any amendment to contentions based on new information . . . could be contrary to the spirit of the Federal Rules"), and *Nautilus* significantly changed the law of indefiniteness; (2) Roche's proposed supplemental contentions raise indefiniteness arguments that it had not raised before; (3) no additional discovery, briefing or other proceedings would be required by Roche's supplemental contentions; and (4) Roche's proposed supplemental contentions were properly and timely raised.

**First**, *Nautilus* represents a significant change in the law of indefiniteness under 35 U.S.C. § 112.<sup>1</sup> District courts across the country have described *Nautilus* as having "altered the

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<sup>1</sup> It is clear that *Nautilus* changed the prevailing law of indefiniteness. In arguing that the Supreme Court merely "clarified" the standard for indefiniteness, Enzo cites to passages from the opinion discussing the *respondent's*

landscape of indefiniteness” and set forth a “new, more rigorous reasonable certainty standard” that is “more stringent” and “stricter than that previously employed by the Federal Circuit.”<sup>2</sup> Patent claims may “have some meaning and [] not [be] insolubly ambiguous” under the Federal Circuit’s pre-*Nautilus* precedent, but nonetheless “fall short of the new, more rigorous reasonable certainty standard under *Nautilus*.” *Abdou*, 2014 WL 6611422, at \*10. Thus, numerous district courts have allowed supplemental briefs, pleadings and discovery responses in light of *Nautilus*.<sup>3</sup>

**Second**, Roche’s supplemental contentions do not repackage invalidity arguments that the Court struck last year. Roche’s proposed contentions present new and distinct arguments for indefiniteness not previously before the Court. Although Enzo is correct that Roche previously made an indefiniteness argument relating to the “Det<sup>b</sup>” term in September 2006 and in October 2013 under the old standard, that argument was premised on the fact that claims 1 and 15 of the ’523 patent define the “Det<sup>b</sup>” term differently, which, of course, renders the term insolubly ambiguous because “the same claim term in the same patent or related patents carries the same construed meaning.” *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003). That argument is not presented in Roche’s proposed supplemental contentions.

With respect to Enzo’s arguments relating to earlier “written description” arguments, there can be no dispute that those arguments were made under *different* statutory provisions and rely on *different* aspects of the claim terms “A<sup>3</sup>” and “Det<sup>b</sup>”. Roche’s initial contentions focused on whether, under the written description requirement of 35 U.S.C. § 112 ¶ 1, the claimed subject matter was adequately described in the patent specification. Roche’s supplemental contentions address the *different* requirement of claim definiteness under § 112 ¶ 2, specifically the fact that the scope of those claim terms, under *Nautilus*, is not reasonably certain if Enzo’s proposed claim constructions are adopted. That Roche’s indefiniteness arguments under *Nautilus* may relate to the same claim terms in previous invalidity arguments does not make those arguments the same.<sup>4</sup>

Indeed, Roche’s supplemental contentions cannot be “identical” to any earlier ones because they are based on a Supreme Court decision that did not previously exist. There is a fundamental difference between proving an “insoluble ambiguity,” *i.e.* an ambiguity that cannot be cured (the old standard), and proving a “zone of uncertainty” as to the scope of the invention (the new standard). While the claim terms “A<sup>3</sup>” and “Det<sup>b</sup>” may not be “insolubly ambiguous” so as to be devoid of meaning, the scope of those terms is reasonably uncertain under *Nautilus* if Enzo’s proposed claim constructions are adopted. *See Abdou*, 2014 WL 6611422, at \*10.

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argument that the “insolubly ambiguous . . . phrase is a shorthand label for a more probing inquiry that the Federal Circuit applies in practice.” The Court considered whether that “may” be true but ultimately rejected the argument, finding that the “insolubly ambiguous” standard “permeate[s] the Federal Circuit’s recent decisions.” *Id.*

<sup>2</sup> *See, e.g., Secure Web Conf. Corp. v. Microsoft Corp.*, 2014 WL 4954644, at \*6 (E.D.N.Y. Oct. 2, 2014); *Abdou v. Alphatec Spine, Inc.*, 2014 WL 6611422, at \*10 (S.D. Cal. Nov. 19, 2014); *Broussard v. Go-Devil Mfg. Co. of La.*, 2014 WL 3377708, at \*41 (M.D. La. July 9, 2014).

<sup>3</sup> *See, e.g., Mycone Dental Supply Co. v. Creative Nail Design, Inc.*, 2014 WL 3362364, at \*3-4 (D.N.J. July 9, 2014); *Adobe Sys. Inc. v. Wowza Media Sys., LLC*, 2014 WL 2731321, at \*1 (N.D. Cal. June 10, 2014); *Tessera, Inc. v. Adv. Micro Devices, Inc.*, No. 05-cv-4063, Dkt. No. 1478 (N.D. Cal. June 30, 2014), Ex. 2.

<sup>4</sup> *See Sitrick v. Dreamworks, LLC*, 2006 WL 6116641, at \*25 & n.11 (C.D. Cal. July 20, 2006) (invalidating term based on indefiniteness, rather than written description, because the issue was “more properly dealt with on grounds of indefiniteness”); *Cyber Acoustics, LLC v. Belkin Int’l, Inc.*, 2014 WL 1225198, at \*20 (D. Or. Mar. 24, 2014) (considering written description and indefiniteness separately and noting the defendant “conflate[d]” the two); *Juxtacomm-Texas Software, LLC v. Axway, Inc.*, 2012 WL 7637197, at \*4 n.3 (E.D. Tex. July 5, 2012) (explaining that claims valid under § 112 ¶ 2 may not be valid under § 112 ¶ 1 because the requirements are distinct).

**Third**, Enzo will not suffer any prejudice if Roche is allowed to serve its supplemental contentions. Enzo does not argue that the supplemental contentions will cause delays in the case schedule, nor does it seek *any* additional discovery or further claim construction briefing. The only prejudice that Enzo alleges is that “Roche’s new contentions . . . change the landscape under which Enzo argued claim construction.” Enzo is incorrect. As an initial matter, there was no opportunity for the parties to previously address *Nautilus* because the Supreme Court decided the case after claim construction briefing was completed. And it is Enzo’s *own* claim construction positions that give rise to the indefiniteness issues identified in Roche’s supplemental contentions. Enzo proposed extremely broad constructions of its patent claims, arguing that the “A<sup>3</sup>” and “Det<sup>b</sup>” terms include any “chain of atoms” and/or “additional atoms or structures,” thereby rendering the scope of those terms uncertain under *Nautilus*. Finally, Roche’s supplemental indefiniteness arguments do not “contradict” its claim construction positions, as Enzo argues. Rather, Roche’s proposed constructions would properly limit the claims and avoid the indefiniteness issues caused by Enzo’s positions. And the *Nautilus* decision was designed to allow for exactly the type of indefiniteness argument that Roche is making in this case: *Nautilus* held that a patent claim is invalid when there is “reasonable uncertainty” over its scope, even if the claim can be construed to “have some meaning and [is] not insolubly ambiguous.” *Abdou*, 2014 WL 6611422, at \*10.

**Finally**, Roche’s supplemental contentions are timely and properly raised, and Enzo mischaracterizes the record in arguing otherwise. This case was initially stayed after the Court allowed Enzo’s prior counsel to withdraw and then, on September 16, the Court asked the parties to propose a schedule for the remainder of the case. Dkt. Nos. 185, 217. In the course of discussing the schedule with Enzo, Roche raised the issue of seeking the Court’s leave to set “a deadline by which Roche will serve supplemental 112 contentions in light of *Nautilus*.” The parties were unable to reach agreement. In their joint letter enclosing the parties’ agreed-upon schedule, the parties indicated that they would continue to discuss the issue. Dkt. No. 218 n.1. The Court entered a scheduling order on October 22, 2014, and Roche gave Enzo a copy its proposed supplemental contentions approximately two weeks later, on November 10, 2014.<sup>5</sup>

**B. Enzo’s Position: Roche’s Untimely November 10, 2014 Invalidity Contentions Are A Second Bite At A Stricken Apple**

On November 12, 2013, this Court granted Enzo’s motion to strike Roche’s untimely supplemental invalidity contentions dated September 17, September 30 and October 16, 2013. (Dkt. No. 129) Roche argued in those contentions that, *inter alia*, Enzo’s ‘523 patent is invalid for failure to provide a sufficient written description of the claim terms “A<sup>3</sup>” and “Det<sup>b</sup>”. However, the Court found that “the time for . . . invalidity contentions concluded in the spring 2013.”

Now, one year later, Roche *again* seeks to add virtually identical invalidity contentions, this time purporting to premise them on a “new standard of indefiniteness” allegedly set forth in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120 (2014). On November 10, 2014, without seeking leave of the Court, Roche *served* Enzo with *signed* “Supplemental Invalidity Contentions Regarding the ‘523 Patent In Light Of *Nautilus*.” On November 18, 2014, Enzo

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<sup>5</sup> Contrary to Enzo’s assertion, Roche did not actually *serve* its supplemental contentions on November 10, 2014—Roche proffered its supplemental contentions pursuant to a request that Enzo *itself* made during a meet-and-confer. To the extent there was any ambiguity in the matter, Roche has since made that clear in correspondence with Enzo.

sent Roche a motion to strike those contentions. Only on November 24, 2014, *after* reviewing Enzo's motion, did Roche contend for the first time that its supplemental invalidity contentions actually were merely a "proposal." Roche asked Enzo to permit Roche to file a motion for leave to supplement instead of Enzo filing a motion to strike. However, regardless of the procedural posture, Roche's latest invalidity contentions should be stricken as an improper request for reconsideration, as well as for several independent reasons.

*First*, Roche's rebranding of its invalidity contentions, and its attempt to bootstrap on *Nautilus*, does not make them any more timely than they were more than a year ago.

Roche's indefiniteness contentions are not new. As early as *September 2006*, Roche argued that the term "Det<sup>b</sup>" rendered indefinite certain claims of the related '440 patent (a parent patent of the '523 patent containing an identical specification). (*See* Ex. 3 at p. 18) Similarly, one of the indefiniteness contentions Roche added on October 16, 2013 was that Det<sup>b</sup> was "insolubly ambiguous and indefinite" in claim 15 of the '523 patent. (Ex. 4 at 11) That contention, made under the "insolubly ambiguous" standard of indefiniteness was stricken as untimely. Thus, Roche's argument that *Nautilus* made indefiniteness easier to challenge is irrelevant in view of the fact that Roche *already* asserted indefiniteness of the claim terms at issue here under the "insolubly ambiguous" standard.

Beyond that, Roche's "new" indefiniteness contentions merely repackage under 35 U.S.C. § 112 paragraph 2 the untimely written description arguments it previously asserted under § 112 paragraph 1. For example, in its October 16, 2013 contentions, Roche asserted pursuant to § 112 paragraph 1 that the '523 patent was invalid because it allegedly lacked a sufficient written description of "A<sup>3</sup>" and "Det<sup>b</sup>". (Exhibit 4 at 9-10) Roche now uses the very same arguments to assert that those terms are indefinite under § 112 paragraph 2. In addition to arguing that "Det<sup>b</sup>" was indefinite in claim 15 (Ex. 4 at 11), Roche argued in its precluded October 16, 2013 contentions that Det<sup>b</sup> was invalid for an insufficient written description because the claims "permit[] Det<sup>b</sup> to contain an unlimited number of intervening atoms between E and Det<sup>b</sup>, or otherwise covalently or non-covalently bonded to Det<sup>b</sup>." (Ex. 4 at 10) In its new contentions, Roche makes a nearly identical argument, but now calls it "indefiniteness" — that "it is not reasonably certain what specific structures and/or chemical bonds define the boundary between 'Det<sup>b</sup>' and 'E'. . . . Det<sup>b</sup> could be defined in any number of different ways. . ." (Ex. 1 at 5) Similarly, on October 16, 2013, Roche made the precluded argument that the written description of "A<sup>3</sup>" encompasses "thousands of compounds." That mirrors its "new" indefiniteness arguments. (*Compare* Ex. 4 at 9 and Ex. 1 at 2, 4) The Court precluded Roche's prior invalidity contentions regarding "A<sup>3</sup>" and "Det<sup>b</sup>" in its November 12, 2013 Order, and the same result should apply here.

*Second*, the Supreme Court's decision in *Nautilus* neither warrants nor justifies Roche's renewed attempt to submit its previously rejected contentions, particularly when applied to the facts of this case. Roche's latest invalidity contentions assert (at 3, 5) that "the '523 patent claims could be understood to cover a nearly infinite, unidentified number of additional atoms or structures." That argument falls squarely within what Roche labels the "old" "insolubly ambiguous" Federal Circuit standard of indefiniteness. Under the "insolubly ambiguous" standard, a claim is indefinite if "reasonable efforts at claim construction result in a definition that does not provide sufficient particularity and clarity to inform skilled artisans of the bounds of the invention." *See, e.g.*, 134 S.Ct. at 2129 (citations omitted). Roche therefore had a full and fair opportunity to timely raise that argument before the Spring 2013 deadline set by the Court,

but failed to do so. Indeed, although Roche now asserts that it “could not have made the indefiniteness arguments in [its November 10, 2014 contentions] . . . under the ‘insolubly ambiguous’ standard,” Roche *already did make* its indefiniteness argument under that very standard in its September 2006 contentions regarding the ‘440 patent and its precluded October 16, 2013 contentions concerning the ‘523 patent.

Furthermore, although *Nautilus* clarified the standard for indefiniteness under 35 U.S.C. § 112 paragraph 2, the Supreme Court cited favorably the Federal Circuit’s statement that a claim is “insolubly ambiguous” when “reasonable efforts at claim construction result in a definition that does not provide sufficient particularity and clarity to inform skilled artisans of the bounds of the invention.” *Id.* at 2129. The Supreme Court closely tracked that standard in *Nautilus*, holding that “a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” 134 S.Ct. at 2123. Thus, it is far from clear that the *Nautilus* standard is “new,” as Roche argues. *Id.* at 2129. Moreover, *Nautilus* did not change the statutory presumption that an issued patent is presumed valid, nor reduce Roche’s burden of showing indefiniteness by clear and convincing evidence. In short, *Nautilus* is not material to the indefiniteness argument Roche now makes.<sup>6</sup>

*Third*, Roche has submitted claim construction briefs and evidence to this Court concerning Enzo’s ‘523 patent that directly contradict the indefiniteness arguments it now asserts. For example, with respect to “Det<sup>b</sup>” the parties briefed the terms “comprising biotin or a substituted or unsubstituted metal chelator or a compound capable of yielding a metal chelator,” “biotin,” and “chelator.” Roche argued, including in four expert declarations, that a person of skill in the art would understand these terms mean specific definitions Roche proposed. (Dkt. Nos. 138, 140, 144, 150, 151, 156) Having stated that a person of skill in the art would define the terms comprising “Det<sup>b</sup>” in a particular way, Roche’s November 10, 2014 indefiniteness contention that “Det<sup>b</sup>” could not be understood with reasonable certainty by a person of skill in the art is, at best, inconsistent. Roche’s new contentions prejudice Enzo because they change the landscape under which Enzo argued claim construction of the ‘523 patent.

*Fourth*, Roche waited more than five months after the *Nautilus* decision to amend its invalidity contentions. If *Nautilus* truly was the impetus for Roche’s new indefiniteness contentions, it should have served them promptly. In *O2 Micro Int’l*, upon which Roche misplaces reliance, the Federal Circuit upheld the district court’s denial of leave to amend infringement contentions because they were made *three* months after the new information was discovered, explaining: “If the parties were not required to amend their contentions promptly after discovering new information, the contentions requirement would be virtually meaningless as a mechanism for shaping the conduct of discovery and trial preparation.” 467 F.3d at 1366.

This Court stated in its November 12, 2013 order that it “has taken a firm position on the deadlines imposed by its Scheduling Order . . . Because more than five months has elapsed since the relevant deadlines, the Court rejects the argument that there is good cause for either party to raise additional contentions.” *A fortiori* Roche’s even more tardy November 10, 2014 indefiniteness contentions should be stricken.

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<sup>6</sup> Roche cites district court decisions discussing the *Nautilus* standard, but they are inapposite. Roche does not cite a single decision that granted (or even considered) leave to supplement where, as here, the allegedly new contentions could have been, and were, made under the “insolubly ambiguous” standard.

Respectfully submitted,

KRAMER LEVIN NAFTALIS & FRANKEL LLP

WILMERHALE LLP

By: /s/ Michael J. Dell

Michael J. Dell  
1177 Avenue of the Americas  
New York, NY 10036  
212-715-9100  
*mdell@kramerlevin.com*

*Attorneys for Enzo Biochem, Inc.  
and Enzo Life Sciences, Inc.*

By: /s/ Robert J. Gunther, Jr.

Robert J. Gunther, Jr.  
7 World Trade Center  
250 Greenwich Street  
New York, NY 10007  
212-230-8830  
*robert.gunther@wilmerhale.com*

*Attorneys for Roche Diagnostics GmbH  
and Roche Molecular Systems, Inc.*